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EXAMINER

AUGHENBAUGH, WALTER

ART UNIT

PAPER NUMBER

1772

5

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/011,659

Applicant(s)

GEORGE ET AL.

Examiner

Walter B Aughenbaugh

Art Unit

1772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) 42-54 and 56-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-41 and 55 is/are rejected.
- 7) ☒ Claim(s) 16-20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_

DETAILED ACTION

*Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-41 and 55, drawn to a reinforced polymeric material formed into an article, classified in class 428, subclass 36.9.
  - II. Claims 42-54, drawn to a reinforced polymer blend, classified in class 525, subclass 92R.
  - III. Claims 56-66, drawn to a method of producing a polymeric material, classified in class 264, subclass 176.1.
2. Inventions II and I are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful as sheeting and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.
3. Inventions III and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be

Art Unit: 1772

used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by a materially different process such as injection molding.

4. Inventions III and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to produce a materially different product such as a reinforced polymer blend of a nanocomposite reinforced polymer and a nanocomposite block copolymer.

5. During a telephone conversation with John J. Kane on February 26, 2003, a provisional election was made without traverse to prosecute the invention of Group I, claims 1-41 and 55. Affirmation of this election must be made by applicant in replying to this Office action. Claims 42-54 and 56-66 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1772

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

*Specification*

9. The abstract of the disclosure is objected to because the last sentence of the abstract pertains to the method of the application, which has been withdrawn as a nonelected invention. The abstract should discuss only the elected invention. Correction is required. See MPEP § 608.01(b).

*Claim Objections*

10. Claims 16-20 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims merely list mechanical properties that are not required, by the language of claim 15, to be included in the vaguely claimed group of mechanical properties that are higher than that of the pure virgin copolymer and the nanocomposite polymer.

*Claim Rejections - 35 USC § 112*

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1, 4-9, 13, 15-23, 27, 33-35, 40 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1772

In regard to claim 1, the phrase “having 0.001 inches to 0.500 inches inside diameter” is indefinite. Please amend to a conventional phraseology for indicating the inside diameter of tubing.

In regard to claim 4, the term “mixture of at least two individual component polymers” is not consistent with the fact that the polymer that is formed from this “mixture” is a copolymer. The cited phraseology suggests that the polymer so formed is a blend when in fact it is a copolymer.

In regard to claim 5, the scope of the composition of the nanocomposite polymer and the pure virgin copolymer intended to be recited by the phrase “said nanocomposite polymer and said pure virgin copolymer share a common chemical segment and matrix” is indefinite.

In regard to claim 6, the chemical structure intended to be recited by the phrase “same crystalline chemical form” is indefinite. Examiner suggests amending to “same crystalline form”.

In regard to claim 7, the language of the claim in its entirety is indefinite. What is the amount of the “metered amounts”? What mechanical properties are predetermined? Note the statements made in the 35 U.S.C. 103 rejection of claim 7 inter alia that this claim consists of method limitations in its entirety, which are given little or no patentable weight in an article claim.

In regard to claim 8, the scope of the composition of the nanocomposite polymer and the pure virgin copolymer intended to be recited by the phrase “said nanocomposite polymer and said pure virgin copolymer share a common chemical family and matrix” is indefinite. The claim is rendered further indefinite given the fact that the terminology used in claim 8 is different

Art Unit: 1772

from that used in claim 5. Is the term “family” recited in claim 8 intended to differentiate the language of claim 8 from the language of claim 5, which uses the term “segment” in the place of “family”? Furthermore, the phrase “to enhance predictability of the mechanical properties of the resultant reinforced polymer blend so formed” is indefinite. What mechanical properties? What are the criteria for “predictability of the mechanical properties”?

In regard to claim 9, please amend “include” in the third line of the claim to “includes”.

Claim 13 recites the limitation "a series of decreasing durometer blends" in second line of the claim. There is insufficient antecedent basis for this limitation in the claim.

In regard to claims 15-20, the phrase “at least some of the mechanical properties of the resultant reinforced polymer blend” is indefinite. What mechanical properties are included in the group of mechanical properties that are higher than that of the pure virgin copolymer and the nanocomposite polymer, and which mechanical properties are excluded from this group? In regard to claims 16-20, which are dependent on claim 15, these claims are not reciting that the respectively claimed properties are included in the vaguely claimed group of mechanical properties that are higher than that of the pure virgin copolymer and the nanocomposite polymer, but are rather merely listing these properties in the group of “mechanical properties” that are not required by the language of the claims to have mechanical properties that are higher than that of the pure virgin copolymer and the nanocomposite polymer. In regard to claim 18, the phrase “with more lubricity with reduced tendency for dust contaminants to adhere thereto” is indefinite; as compared to the lubricity and tendency for dust contaminants to adhere of what? In regard to claim 19, the phrase “with enhanced lubricity” is indefinite; as compared to lubricity of what?

Art Unit: 1772

In regard to claim 21, the scope of the compositions intended to be recited by “nylon based” cannot be ascertained.

In regard to claim 22, the scope of the compositions intended to be recited by “polyamide-based” (recited in the second and fourth lines of the claim) cannot be ascertained.

In regard to claim 23, the scope of the compositions intended to be recited by “polyester-based” (recited in the second and fourth lines of the claim) cannot be ascertained.

In regard to claim 27, the phrase “at least partially translucent” is indefinite, the scope of the claim cannot be ascertained.

Claim 33 recites the limitation “ink used for printing” in the third line of the claim. There is insufficient antecedent basis for this limitation in the claim.

In regard to claim 34, the term “homopolymer” renders the phrase “reinforced homopolymer nanocomposite material” indefinite because the “reinforced homopolymer nanocomposite material” is a blend of a homopolymer and a pure virgin material and therefore the use of the term “homopolymer” to describe the blend is indefinite. The scope of the pure virgin copolymers intended to be recited by the phrase “the pure virgin copolymers are similar chemically to the homopolymer” is indefinite due to the phrase “similar chemically”.

In regard to claim 35, amend “materials is” to “material is”.

Claim 40 contains the trademark/trade name Pebax. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used to properly identify any particular material or product. A trademark or

Art Unit: 1772

trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name.

In regard to claim 55, the scope of the composition of the nanocomposite polymer and the pure virgin polymer intended to be recited by the phrase "nanocomposite polymer with its analogous pure virgin polymer" is indefinite due to the recitation of the term "analogous".

*Claim Rejections - 35 USC § 103*

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims 1-9, 13, 15-17, 19-23, 25, 29-32, 34-41 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bagaoisan et al. in view of Beall et al.

In regard to claims 1-3, Bagaoisan et al. teach a catheter which comprises an elongate flexible tubular body (item 16, Fig. 1 and 4) having a main lumen (item 30, Fig. 2-4) (col. 3, lines 59-64). Bagaoisan et al. teach that the tubular body has an internal diameter of about 0.10

Art Unit: 1772

inches (col. 5, lines 26-40). Bagaoisan et al. teach that the tubular body is formed of nylon (in regard to claim 1) or of a blend of Pebax (TM) copolymer and nylon (in regard to claim 2) (col. 3, lines 6-8), and that different materials are blended to select for desirable flexibility properties (col. 9, lines 12-20). Pebax (TM) is known as a group of nylon/polyether copolymers, as evidenced by Applicant's specification, page 19, lines 25-26. Bagaoisan et al. therefore teach a blend of a polymer (nylon) with a pure virgin copolymer (nylon/polyether copolymer without particles included in the blend). In regard to the recitation that the polymer blend is "formed by extruding" the two polymers into tubing, the method of forming the tubing is not germane to the issue of patentability of the tubing itself. Therefore, this limitation has not been given patentable weight.

Bagaoisan et al. fail to teach that the nylon polymer (in regard to claim 1) or the nylon polymer blended with the nylon/polyether copolymer (in regard to claim 2) is a nanocomposite polymer, thus resulting in a reinforced polymer blend.

Beall et al., however, disclose a matrix polymer/platelet nanocomposite (col. 1, lines 65-66) material for use where it is desired to alter one or more physical properties of a matrix polymer, such as elasticity characteristics (col. 1, lines 33-43). Beall et al. disclose that nanoscale platelet particles (nanoparticles as claimed by Applicant in claim 3) of high strength and modulus dispersed throughout a polymer matrix imparts greater mechanical reinforcement to the polymer matrix than do comparable loadings of conventional reinforcing fillers of micron-scale size (col. 6, lines 32-39). Beall et al. disclose that nylons such as nylon 6, nylon 11 and nylon 12 are useful as the matrix polymer (col. 18, lines 28-37). Therefore, one of ordinary skill in the art would have recognized to have blended the nanoscale platelet particles of Beall et al.

with the nylon polymer of Bagaoisan et al. in order to impart superior mechanical reinforcement to the nylon polymer matrix of Bagaoisan et al. and to form a nanocomposite polymer, as taught by Beall et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have blended the nanoscale platelet particles of Beall et al. with the nylon polymer of Bagaoisan et al. in order to impart superior mechanical reinforcement to the nylon polymer matrix of Bagaoisan et al. and to form a nanocomposite polymer, as taught by Beall et al.

In regard to claim 4, the nylon/polyether copolymer (Pebax (TM)) taught by Bagaoisan et al. is a pure virgin copolymer that comprises a reacted plastic material formed from a mixture of at least two individual component polymers, i.e., nylon and polyether. As Bagaoisan et al. teach that different materials are blended to select for desirable flexibility properties (col. 9, lines 12-20), Bagaoisan et al. teach that the individual component polymers provide the reinforced polymer blend with at least some mechanical properties attributable to each of the individual component polymers.

In regard to claim 5, the nanocomposite polymer taught by Bagaoisan et al. and Beall et al. is a nylon and the pure virgin copolymer taught by Bagaoisan et al. is a nylon/polyether copolymer; therefore, the nanocomposite polymer and the pure virgin copolymer share a common chemical segment and matrix, i.e. nylon.

In regard to claim 6, as Bagaoisan et al. teach that a nylon/polyether copolymer is blended with nylon, one of ordinary skill in the art would have recognized to have used nylons having the same crystalline chemical form as the nylons in the nylon/polyether copolymer and

Art Unit: 1772

the nylon nanocomposite as taught by Bagaoisan et al. and Beall et al. in order to enhance the compatibility between the nylon/polyether copolymer and the nylon nanocomposite.

In regard to claim 7, the recitation "said pure virgin copolymer is added to said nanocomposite polymer in metered amounts to predetermine the mechanical properties of the resultant reinforced polymer blend so formed" is a method limitation; the method of forming the tubing is not germane to the issue of patentability of the tubing itself. Therefore, this limitation has not been given patentable weight, and consequently, claim 7 and the claims dependent upon claim 7, have been given little patentable weight.

In regard to claim 8, the nanocomposite polymer taught by Bagaoisan et al. and Beall et al. is a nylon and the pure virgin copolymer taught by Bagaoisan et al. is a nylon/polyether copolymer; therefore, the nanocomposite polymer and the pure virgin copolymer share a common chemical family and matrix, i.e. nylon, and one of ordinary skill in the art would have recognized that it is notoriously well known that the predictability of the mechanical properties of polymeric blends is enhanced when the components of a blend share a common chemical species. Furthermore, the functional language phrase "to enhance the predictability of the mechanical properties of the resultant polymer blend so formed" has been given little patentable weight. The phrase "to enhance the predictability of the mechanical properties of the resultant polymer blend so formed" is a method limitation that has been given little patentable weight since the "enhance[d] predictability of the mechanical properties" of a "resultant polymer blend" that is the result of a step that is taken during the process of forming the blend.

Art Unit: 1772

In regard to claim 9, the nanocomposite polymer taught by Bagaoisan et al. and Beall et al. includes nylon and the pure virgin nylon/polyether copolymer taught by Bagaoisan et al. includes nylon.

In regard to claim 13, the recitation “wherein a series of decreasing durometer blends are produced with similar melting points for advantages in forming composite guide catheters” is a method limitation; the method of forming the tubing is not germane to the issue of patentability of the tubing itself. Therefore, this limitation has not been given patentable weight, and consequently, claim 13 has been given little patentable weight.

In regard to claims 15-17, Bagaoisan et al. and Beall et al. teach the tubing as discussed above. Beall et al. further disclose that the nanocomposite film is biaxially stretched to increase the modulus and dimensional stability of the film over the values of those properties of the unstretched nanocomposite film (col. 21, line 54-col. 22, line 4). One of ordinary skill in the art would have recognized to have biaxially stretched the reinforced polymer blend taught by Bagaoisan et al. and Beall et al. in order to increase the modulus (i.e. stiffness) and dimensional stability of the reinforced polymer blend to values which are greater than the those values of the nanocomposite polymer of Beall et al. (and therefore greater than the stiffness of the nylon/polyether copolymer since the stiffness of nylon/polyether copolymer is less than that of nylon). The teaching of Beall et al. pertaining to modulus (stiffness) and dimensional stability satisfies the limitations of claim 15 that “at least some of the mechanical properties of the resultant reinforced polymer blend are higher than the same mechanical properties of the pure virgin copolymer and the nanocomposite polymer”.

Art Unit: 1772

In regard to claim 19, Bagaoisan et al. teach that nylon and nylon/polyether copolymer (Pebax, TM) are both lubricious materials (col. 5, lines 45-51) and therefore, one of ordinary skill in the art would have recognized that use of these lubricious materials would provide for ease of catheter placement and movement.

In regard to claims 19-20, the phraseology of claims 15 and 19-20 does not require that the properties of lubricity (as claimed in claim 19) and ductility (as claimed in claim 20) of the blend are higher than the same mechanical properties of the pure virgin copolymer and the nanocomposite polymer. See the discussion in regard to the 35 U.S.C. 103(a) rejection of claims 15-20.

In regard to claim 20, the reinforced polymer blend taught by Bagaoisan et al. and Beall et al. has ductility as a mechanical property, as ductility is a property that all polymeric materials possess in some degree.

In regard to claim 21, the pure virgin nylon/polyether copolymer of Bagaoisan et al. is nylon based.

In regard to claim 22, the nanocomposite polymer taught by Bagaoisan et al. and Beall et al. is polyamide based.

In regard to claim 23, Bagaoisan et al. teach that the tubular body is formed of a blend of pure virgin nylon/polyether copolymer (Pebax TM) and Hytrel TM (col. 9, lines 15-20), disclosed as a family of polyester block ethers in page 25, lines 19-22 of Applicant's specification. Furthermore, Beall et al. disclose that polyesters, the type of which is not critical, as suitable matrix polymers as the nanocomposite material of Beall et al. (col. 18, lines 41-53). Therefore, one of ordinary skill in the art would have recognized to have blended the nanoscale

Art Unit: 1772

platelet particles of Beall et al. with the polyester block ether of Bagaoisan et al. in order to impart superior mechanical reinforcement to the polyester block ether polymer matrix of Bagaoisan et al. as taught by Beall et al., and to have replaced this nanocomposite polyester-based polymer with the nylon nanocomposite of Bagaoisan et al., since Bagaoisan et al. establish both nylon and polyester block ethers as suitable materials for blending with nylon/polyether copolymer.

In regard to claim 25, the limitation “said Nylon 12 pure virgin copolymer is added to said nanocomposite polymer in pre-specified amounts in order to predetermine hardness of the resultant reinforced polymer blend so formed” is a method limitation and has not been given patentable weight since the method of forming the tubing is not germane to the issue of patentability of the tubing itself.

Claims 29-32 consist solely of method limitations which have not been given patentable weight since the method of forming the tubing is not germane to the issue of patentability of the tubing itself.

In regard to claim 34, the blend of nylon and nylon/polyether copolymer taught by Bagaoisan et al. and Beall et al. is a reinforced homopolymer nanocomposite material wherein the pure virgin copolymers (nylon/polyether copolymer) are similar chemically to the homopolymer (nylon) in the reinforced homopolymer nanocomposite material in that the pure virgin copolymer includes the homopolymer, i.e., nylon. The limitation “with prespecified strength parameters controlled by the metered amount of pure virgin copolymers added thereto” is a method limitation and is not given patentable weight since the method of forming the nanocomposite material is not germane to the issue of patentability of the nanocomposite

Art Unit: 1772

material itself. Nonetheless, note again that Bagaoisan et al. teach that different materials are blended to select for desirable flexibility properties (col. 9, lines 12-20).

In regard to claim 35, Beall et al. teaches that prior art nanocomposite material has been formed into pellets (col. 1, line 65-col. 2, line 29). Therefore, one of ordinary skill in the art would have recognized to have formed the nanocomposite material taught by Bagaoisan et al. and Beall et al. into pellets since it is notoriously well known to do so as taught by Beall et al.

In regard to claim 36, Bagaoisan et al. and Beall et al. teach the catheter formed from a blend as discussed above. The limitation “wherein the ductility thereof is controlled by the relative amount of pure virgin polymer extruded with a nanocomposite reinforced copolymer” is a method limitation and has therefore been given little patentable weight since the method of forming the catheter is not germane to the issue of patentability of the catheter itself. In regard to the limitation that the nanocomposite is a nanocomposite reinforced *copolymer*, Bagaoisan et al. teach that the tubular body is formed of a blend of pure virgin nylon/polyether copolymer (Pebax™) and Hytrel™ (col. 9, lines 15-20), disclosed as a family of polyester block ethers in page 25, lines 19-22 of Applicant’s specification. Furthermore, Beall et al. disclose that polyesters or copolyesters (col. 18, lines 54-55), the type of which is not critical, as suitable matrix polymers as the nanocomposite material of Beall et al. (col. 18, lines 41-53). Therefore, one of ordinary skill in the art would have recognized to have blended the nanoscale platelet particles of Beall et al. with the polyester block ether copolymer of Bagaoisan et al. in order to impart superior mechanical reinforcement to the polyester block ether copolymer polymer matrix of Bagaoisan et al. as taught by Beall et al., and to have replaced the nylon nanocomposite of Bagaoisan et al. with this nanocomposite polyester-based copolymer, since Bagaoisan et al. establish both nylon

Art Unit: 1772

and polyester block ether copolymers as suitable materials for blending with nylon/polyether copolymer.

Claims 37 and 38 consist solely of method limitations and have therefore been given no patentable weight since the method of forming the catheter is not germane to the issue of patentability of the catheter itself.

In regard to claims 39 and 40, the limitation “formed by extruding a first nanocomposite polymer with a second nanocomposite polymer” is a method limitation and has been given little patentable weight since the method of forming the tubing is not germane to the issue of patentability of the tubing itself. Nonetheless, Bagaoisan et al. teach the tubular body formed from a blend of Pebax (TM) copolymer and nylon (col. 3, lines 6-8) as discussed above. Bagaoisan et al. fail to teach that the nylon polymer and the nylon/polyether copolymer are both nanocomposite polymers. Beall et al., however, disclose a matrix polymer/platelet nanocomposite (col. 1, lines 65-66) material for use where it is desired to alter one or more physical properties of a matrix polymer, such as elasticity characteristics (col. 1, lines 33-43). Beall et al. disclose that nanoscale platelet particles (nanoparticles as claimed by Applicant in claim 3) of high strength and modulus dispersed throughout a polymer matrix imparts greater mechanical reinforcement to the polymer matrix than do comparable loadings of conventional reinforcing fillers of micron-scale size (col. 6, lines 32-39). Beall et al. disclose that nylons such as nylon 6, nylon 11 and nylon 12 and copolyamides (col. 17, line 57-col. 18, line 12) are useful as the matrix polymer (col. 18, lines 28-37). Therefore, one of ordinary skill in the art would have recognized to have blended the nanoscale platelet particles of Beall et al. with the nylon polymer and the nylon/polyether copolyamide of Bagaoisan et al. in order to impart superior

Art Unit: 1772

mechanical reinforcement to the nylon polymer and the nylon/polyether copolyamide of Bagaoisan et al. to form nanocomposite polymers, as taught by Beall et al.

In regard to claim 41, Bagaoisan et al. and Beall et al. teach the blend of a nanocomposite polymer and a pure virgin copolymer as discussed above. The limitation “formed by extruding a nanocomposite polymer with a pure virgin copolymer into pellets” is a method limitation and is given little patentable weight since the method of forming the pellets is not germane to the issue of patentability of the pellets themselves. Beall et al. teaches that prior art nanocomposite material has been formed into pellets (col. 1, line 65-col. 2, line 29). Therefore, one of ordinary skill in the art would have recognized to have formed the nanocomposite material taught by Bagaoisan et al. and Beall et al. into pellets since it is notoriously well known to do so as taught by Beall et al.

In regard to claim 55, Bagaoisan et al. and Beall et al. teach the blend of a nanocomposite polymer and a pure virgin polymer formed into tubing having an inside diameter of 0.001 to 0.500 inches as discussed above. The pure virgin nylon/polyether copolymer is analogous to the nanocomposite nylon polymer in that the pure virgin polymer includes the nylon polymer of the nanocomposite polymer, i.e., nylon. The limitation “formed by extruding a nanocomposite polymer with its analogous pure virgin polymer into tubing” is a method limitation and is given little patentable weight since the method of forming the tubing is not germane to the issue of patentability of the tubing itself.

15. Claims 10-12, 24 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bagaoisan et al. in view of Beall et al., and in further view of Tse et al.

In regard to claims 10-12, Bagaoisan et al. and Beall et al. teach the tubing as discussed above. Beall et al. discloses that nylon 6, nylon 11 or nylon 12 are useful as the polymer of the nanocomposite polymer material (col. 18, lines 28-37). Bagaoisan et al. teach a nylon/polyether copolymer as the pure virgin copolymer as claimed as discussed above. Bagaoisan et al. and Beall et al. fail to explicitly teach that the pure virgin copolymer includes nylon 6, nylon 11 or nylon 12. Tse et al., however, teach that nylon 6, nylon 11 or nylon 12 are suitable polyamides for use in polyether/polyamide copolymer (Pebax, TM) copolymers (col. 3, line 67-col. 4, line 21). Therefore, one of ordinary skill in the art would have recognized to have used nylon 6, nylon 11 or nylon 12 as the nylon of the nylon/polyether copolymer of Bagaoisan et al., since the use of nylon 6, nylon 11 or nylon 12 as the polyamide of a polyamide/polyether copolymer is notoriously well known as taught by Tse et al. In regard to the limitation of claims 10-12 that the blend is composed of a nanocomposite polymer that includes nylon 6, nylon 11 or nylon 12 and a pure virgin copolymer that includes the same nylon that is included in the nanocomposite polymer, one of ordinary skill in the art would have recognized to have mixed a nanocomposite polymer and a polyamide/polyether copolymer which both include the same nylon, e.g. a nanocomposite polymer having a nylon 6 matrix with a polyether/nylon 6 copolymer, when forming the blend to enhance compatibility between the two components since it is notoriously well known to one of ordinary skill in the art that compatibility between components in a blend is enhanced when mixing components that share like polymer chains or chain segments.

In regard to claim 24, Bagaoisan et al., Beall et al. and Tse et al. teach the tubing of a blend of nylon 12 nanocomposite polymer and nylon 12/polyether pure virgin copolymer as discussed above. Furthermore, Beall et al. disclose that loadings of platelet nanoparticles in a

Art Unit: 1772

matrix polymer such as nylon 12 (col. 18, lines 28-37) in a range of about 0.05% to about 40% by weight, preferably about 0.5% to about 20%, more preferably about 1% to about 10% of the composite material significantly enhances modulus, dimensional stability and wet strength (col. 15, lines 16-20).

In regard to claim 35, Tse et al. disclose that polymeric blends are formed by dry blending pellets of each polymeric component of the blend and are then consequently extruded to form the blend (col. 8, lines 46-54). Therefore, one of ordinary skill in the art would have recognized to have formed the nanocomposite material taught by Bagaoisan et al. and Beall et al. into pellets in order to preserve the nanocomposite material in a form that would be used to form a blend of the nanocomposite material taught by Bagaoisan et al. and Beall et al. and another polymeric material, as it is notoriously well known to initiate formation of a blend of two polymeric components by dry blending pellets of the two components as taught by Tse et al.

16. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bagaoisan et al. in view of Beall et al., and in further view of Wijayarathna et al.

Bagaoisan et al. and Beall et al. teach the tubing as discussed above. Bagaoisan et al. and Beall et al. fail to teach that the mechanical properties of the resultant reinforced polymer blend are intermediate between the mechanical properties of the pure virgin copolymer and the nanocomposite polymer. Tse et al., however, disclose a catheter having a tip consisting of a blend of nylon and polyether block amide copolymer (i.e., polyether/polyamide copolymer or Pebax, TM). Tse et al. discloses that nylon is blended with the flexible polyether block amide copolymer in order to increase the strength and stiffness of the tip while maintaining substantial softness and flexibility (col. 3, lines 14-22). Therefore, one of ordinary skill in the art would

Art Unit: 1772

have recognized that the mechanical properties of the reinforced polymer blend are intermediate between the mechanical properties of the pure virgin copolymer and the nanocomposite polymer, since Tse et al. establish that the blending of nylon with polyether block amide copolymer results in a polymer blend of strength and stiffness intermediate to that of nylon and polyether block amide copolymer.

17. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bagaoisan et al. in view of Beall et al., and in further view of Havens.

Bagaoisan et al. and Beall et al. teach the tubing as discussed above. Bagaoisan et al. further teach that nylon and nylon/polyether copolymer (Pebax, TM) are both lubricious materials (col. 5, lines 45-51). Bagaoisan et al. and Beall et al. fail to teach that the reinforced polymer blend has reduced tendency for dust contaminants to adhere thereto. Havens discloses that nylon/polyether copolymer (Pebax, TM) polymers are antistatic (col. 4, lines 4-14) and therefore prevent accumulation of dust (col. 1, lines 33-54). Therefore, one of ordinary skill in the art would have recognized that blending of a suitable lubricious nylon/polyether copolymer with a lubricious nylon would reduce the tendency of dust contaminants to adhere to a tubing of the reinforced polymer blend due to the antistatic nature of certain nylon/polyether copolymers as taught by Havens.

In further regard to claim 18, the phraseology of claims 15 and 18 does not require that the property of lubricity of the blend is higher than the same mechanical property of the pure virgin copolymer and the nanocomposite polymer. See the discussion in regard to the 35 U.S.C. 103(a) rejection of claims 15-20.

Art Unit: 1772

18. Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bagaoisan et al. in view of Beall et al., and in further view of Tse et al., and in further view of Wang et al.

Bagaoisan et al., Beall et al. and Tse et al. teach the tubing as discussed above.

In regard to claim 26, Tse et al. also teaches that a film including a layer of a blend that is clear (i.e. that exhibits a low level of haze) is indicative of functional compatibility between the materials (col. 2, lines 45-49). Bagaoisan et al., Beall et al. and Tse et al. fail to explicitly teach that the blend is transparent or at least partially translucent. Wang et al., however, teach that both nylon 12 and Pebax 3533 are clear materials (col. 11, lines 1-5). Therefore, one of ordinary skill in the art would have recognized to have blended two clear, compatible polymeric materials such as nylon 12 and Pebax 3533 in order to produce a clear (i.e. transparent) blend as taught by Tse et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have blended two clear, compatible polymeric materials such as nylon 12 and Pebax 3533 in order to produce a clear (i.e. transparent) blend as taught by Tse et al.

In regard to claim 27, a material that is "at least partially translucent" as claimed by Applicant would be considered to be transparent, i.e. would be considered to exhibit a low level of haze as taught by Tse et al.

19. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bagaoisan et al. in view of Beall et al., and in further view of Wang et al.

Bagaoisan et al. and Beall et al. teach the tubing as discussed above. Bagaoisan et al. and Beall et al. fail to teach that the tubing is opaque. Wang et al., however, teaches the addition of

Art Unit: 1772

radiopaque particles to a polymeric material used to form medical instruments such as catheters to render the catheter radiopaque (col. 8, lines 47-50). Therefore, one of ordinary skill in the art would have recognized to have added radiopaque particles to the blend of Bagaoisan et al. and Beall et al. in order to render the blend radiopaque as taught by Wang et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have added radiopaque particles to the blend of Bagaoisan et al. and Beall et al. in order to render the blend radiopaque as taught by Wang et al.

20. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bagaoisan et al. in view of Beall et al., and in further view of Bansleben et al.

Bagaoisan et al. and Beall et al. teach the tubing as discussed above. Bagaoisan et al. and Beall et al. fail to teach that the nanocomposite polymer increases the adherence of ink used for printing on the exterior of any product formed from the resultant nanocomposite reinforced polymer blend material. Bansleben et al., however discloses that polymers including amide groups provide a material which has good ink adhesion properties to permit printing thereon (col. 13, lines 57-60). As the nanocomposite polymer of Bagaoisan et al. and Beall et al. is a nylon such as nylon 6, nylon 11 or nylon 12 (which are polyamides), one of ordinary skill in the art would have recognized that the nylon nanocomposite polymer would increase the adherence of ink to permit printing thereon since polymers including amide groups provide a material which has good ink adhesion properties to permit printing thereon as taught by Bansleben et al.

Art Unit: 1772

*Conclusion*



21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,527,325 to Conley et al. (note col. 10, lines 23-28). Also note col. 8, lines 13-26 of US 4,899,521 to Havens, which was relied upon in the rejection of claim 18.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B Aughenbaugh whose telephone number is 703-305-4511. The examiner can normally be reached on Monday-Friday from 9:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on 703-308-4251. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

wba  
03/06/03 WBA

  
HAROLD PYON  
SUPERVISORY PATENT EXAMINER  


3/7/03